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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,369	08/29/2001	Ahmad Yekta	1191/1H584-US1	9064

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EXAMINER	
NILAND, PATRICK DENNIS	
ART UNIT	**PAPER NUMBER**
1714	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,369	YEKTA ET AL.	
	Examiner	Art Unit	
	Patrick D. Niland	1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment of 11.26.03 has been entered. Claims 1-31 are pending.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6, 8-23, and 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by US Pat. No. 6485703 Cote et al..

Cote discloses the instantly claimed composition at the abstract; column 6, lines 9-67; column 7, lines 45-47, which will necessarily give a viscosity change with pH change and/or with temperature change; column 8, lines 27-44; and the remainder of the document. The polymers will be amorphous and are therefore liquid by definition. Column 9, lines 55-65 falls within the scope of the instant claims 8-9. The mixture will necessarily be placed into an instrument's container, which falls within the scope of the instant claims 13-23 and 27. The applicant's argument re "consisting essentially of" is not persuasive because the component that the applicant states that they wish to exclude of Cote is the component which falls within the scope of the instantly claimed viscosity changing polymers. The instant claims do not exclude the properties argued by the applicant. "Consisting essentially of" does not exclude any other component of

the patentee because no other component has been shown to materially affect the basic and novel characteristics of the instant claims. The applicant has not shown the additional ingredients of the reference to materially affect the basic and novel characteristics of the composition. It is therefore not seen that "consisting essentially of" excludes anything from the composition of the reference. See In re Janakirama-Rao, 317 F 2d 951, 137 USPQ 893 (CCPA 1963) and Ex parte Davis et al., 80 USPQ 448 (PTO Bd. App. 1948). The "gelling" step of the newly added claims necessarily occurs in the polymer of the patentee because it is a hydrogel. The argument that the patentee does not disclose or suggest a process for preparing a standard, or a process for preparing a container for calibrating an instrument, comprising gelling a mixture and therefore, Cote does not anticipate claims 17-23 and 27 is not persuasive because the patentee performs the instantly claimed method steps. The recited future intended use of the resulting product of the method of the patentee and the instant claims is not material in determining whether the process of the instant claims 17-23 and 27 is novel because it does not further limit the process of the instant claims so as to remove the process of the patentee as anticipating it because the product resulting from the process of the patentee necessarily and inherently can be used in these future processes and the product of the process of the patentee will be in some type of container. This rejection is therefore maintained.

4. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6485703 Cote et al. in view of US Pat. No. 6077669 Little et al..

Cote discloses the instantly claimed composition at the abstract; column 6, lines 9-67; column 7, lines 45-47, which will necessarily give a viscosity change with pH change and/or with temperature change; column 8, lines 27-44; and the remainder of the document. The polymers will be amorphous and are therefore liquid by definition. Column 9, lines 55-65 falls within the scope of the instant claims 8-9. The mixture will necessarily be placed into an instrument's container, which falls within the scope of the instant claims 13-23 and 27. It would have been obvious to one of ordinary skill in the art to use the HASE polyurethanes of the instant claims because they are well known, commercially available hydrogel forming polymers and the patentee encompasses such polyethylene oxide based hydrogel forming polymers at column 6, lines 9-12 and 17-21. It would have been obvious to one of ordinary skill in the art to calibrate an instrument using these mixtures because the ordinary skilled artisan would recognize that the reading of the mixture without analyte must be determined to compare it with analyte containing material so that a meaningful value can be assigned to the analyte containing reading. This would be calibration or standardization and is discussed at column 8 of Little et al.. It would have been obvious to one of ordinary skill in the art to use ammonia gas to achieve whatever the desired pH should be because this is a well known manner to affect pH and would be readily applicable to the systems of Cote. The applicant's argument re "consisting essentially of" is not persuasive because the component that the applicant states that they wish to exclude of Cote is the component which falls within the scope of the instantly claimed viscosity changing polymers. The instant claims do not exclude the properties argued by the applicant. "Consisting

essentially of" does not exclude any other component of the patentee because no other component has been shown to materially affect the basic and novel characteristics of the instant claims. The applicant has not shown the additional ingredients of the reference to materially affect the basic and novel characteristics of the composition. It is therefore not seen that "consisting essentially of" excludes anything from the composition of the reference. See In re Janakirama-Rao, 317 F 2d 951, 137 USPQ 893 (CCPA 1963) and Ex parte Davis et al., 80 USPQ 448 (PTO Bd. App. 1948). The "gelling" step of the newly added claims necessarily occurs in the polymer of the patentee because it is a hydrogel. The argument that the patentee does not disclose or suggest a process for preparing a standard, or a process
for preparing a container for calibrating an instrument, comprising gelling a mixture and therefore, Cote does not anticipate claims 17-23 and 27 is not persuasive because the patentee performs the instantly claimed method steps. The recited future intended use of the resulting product of the method of the patentee and the instant claims is not material in determining whether the process of the instant claims 17-23 and 27 is novel because it does not further limit the process of the instant claims so as to remove the process of the patentee as anticipating it because the product resulting from the process of the patentee necessarily and inherently can be used in these future processes and the product of the process of the patentee will be in some type of container. The applicant's arguments regarding whether or not Little discloses viscosity changing polymers is not persuasive because all polymers have the ability to change viscosity with some changing environmental factor such as temperature, pH, etc.. This

argument ignores the reason for which Little was clearly cited above and the fact that Cote is the primary reference cited for this factor with Little cited to explain, as stated above. This rejection is therefore maintained.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Niland whose telephone number is (571) 272-1121. The examiner can normally be reached on Monday through Thursday from 10 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The fax phone

number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

pn

February 22, 2004

Patrick Niland
Primary Examiner
Art Unit 1714